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Paper 30
Entered: September 25, 2014

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BECTON, DICKINSON AND COMPANY,
Petitioner,

v.

ONE STOCKDUQ HOLDINGS, LLC,
Patent Owner.

Case IPR2013-00235
Patent 5,704,914

Before KEVIN F. TURNER, BRIAN J. McNAMARA, and KEVIN W. CHERRY, *Administrative Patent Judges.*

CHERRY, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. BACKGROUND

On April 4, 2013, Becton, Dickinson and Company ("Petitioner") filed a Petition ("Pet.") to institute an *inter partes* review of claims 22–26, 28, 29, and 31 (the "challenged claims") of U.S. Patent No. 5,704,914 ("the '914 patent"). Paper 4. On July 5, 2013, One StockDuq Holdings, LLC ("Patent Owner") filed a Preliminary Response ("Prelim. Resp."). Paper 9. On October 1, 2013, the Board instituted a trial for all challenged claims on less than all of the grounds of unpatentability alleged in the Petition. Paper 10 ("Dec. to Institute").

After institution of the trial, Patent Owner filed a Substitute Patent Owner's Response ("PO Resp."; Paper 23)[1] to which Petitioner replied ("Pet. Reply;" Paper 24).

Oral hearing was held on July 7, 2014. A transcript is entered as Paper 29 ("Tr.").

A. The '914 Patent (Ex. 1001)

The '914 patent generally relates to the field of catheter assemblies used to place a catheter into a liquid containing region such as a blood vessel (i.e., intravenous or IV). Ex. 1001, col. 1, ll. 1–8. As described in the Background of the Invention, catheter assemblies long have been known. *Id.* at col. 1, ll. 14–16. Yet the inventors of the '914 patent perceived that there were problems with the prior art catheter assemblies that could be improved upon. One such problem was the possibility of an accidental needle stick, because some of the prior art assemblies allowed the needle to be exposed during the catheterization process. *Id.* at col. 1, ll. 45–50. Another perceived issue was contamination arising from the

[1] Patent Owner filed a Patent Owner's Response (Paper 17) which was corrected, without objection, and refiled as Substitute Patent Owner's Response (Paper 23).

possibility of blood leakage from the needle during the catheterization process or as a result of blood flashback. *Id.* at col. 1, l. 50–col. 2, l. 3.

The inventors have attempted to resolve these issues and other perceived shortcomings via the catheter assembly depicted in Figure 4 of the '914 patent, reproduced below, with color and labels added for the convenience of the reader:

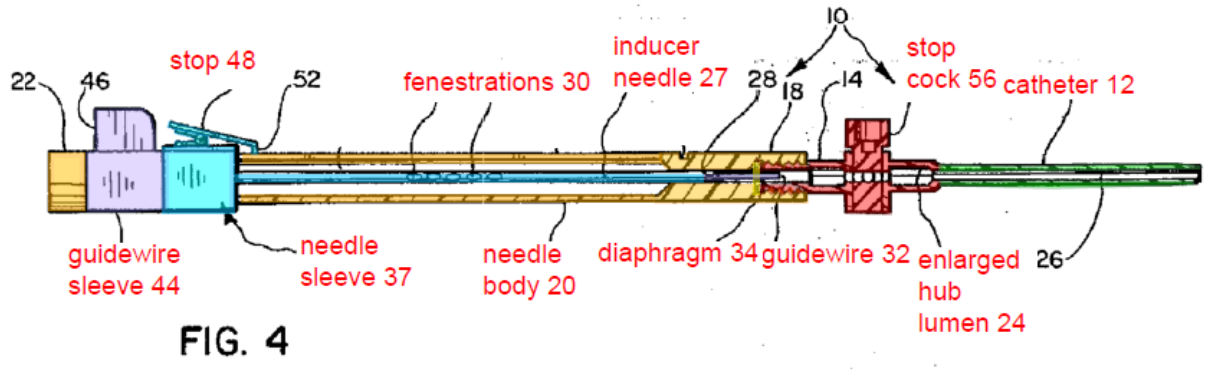

FIG. 4

Figure 4 of the '914 patent depicts a catheter assembly.

The catheter assembly is made up of three primary portions—catheter 12 (green), catheter hub 14 (red), and needle body 20 (orange). In use, stop 48 is released and needle 27 is advanced via needle sleeve 37. As needle 27 is advanced, it passes through diaphragm 34 (yellow) which may contain a deformable slit. Needle 27 is inserted in the patient and blood flashback can be observed in enlarged hub lumen 24 as needle 27 contains fenestrations 30 which allow blood flowing up needle cannula 26 to fill enlarged hub lumen 24. Diaphragm 34 prevents the blood from flowing past catheter hub lumen 14. Next, guidewire 32 is advanced via guidewire sleeve 44 as depicted in Figure 3 of the '914 patent, reproduced below with color and labels added for the convenience of the reader:

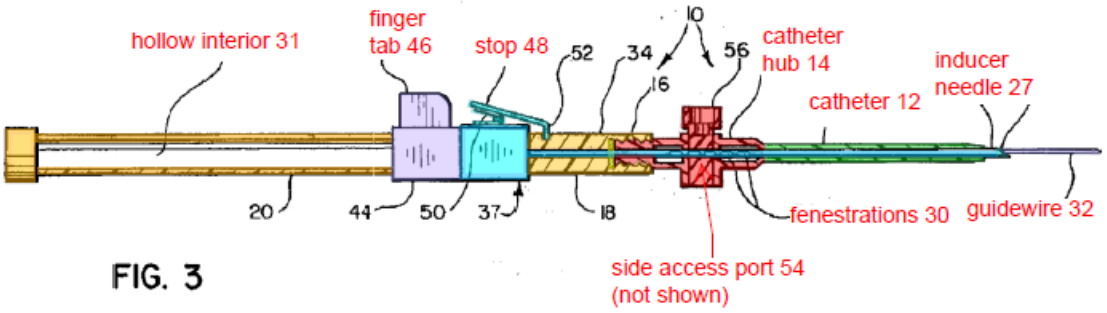

FIG. 3

Figure 3 depicts a catheter assembly.

If there is no resistance on guidewire 32, catheter 12 is inserted into the patient while simultaneously holding down stop 48 so that, as catheter 12 is being inserted, needle 27 and guidewire 32 do not advance into the patient any further. Needle 27 and guidewire 32 then are retracted fully and needle body 20 is removed, leaving catheter 12 and catheter hub lumen 14 attached to the patient. A side access port 54 also may be provided, but is not visible in Figure 3 as the port is perpendicular to the page. *See id.* at col. 5, l. 65 – col. 6, l. 49.

B. Illustrative Claim

Claims 22 and 31 are the independent claims at issue of the ’914 patent. Claim 31 is illustrative of the claims and recites (bracketed material added):

31. A catheter assembly comprising:

a flexible catheter defining a passageway which extends between open proximal and distal ends[;]

a catheter hub having a distal end attached to a proximal end of said catheter, said hub defining a lumen which extends between open proximal and distal ends and which communicates on a distal end thereof with said passageway[;]

a flexible, resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle, said diaphragm being attached to said hub to seal a proximal end of said hub lumen in a liquid tight manner for preventing a liquid which has been

introduced into said hub lumen from said catheter, external to a needle which may be penetrating said diaphragm and projecting into said hub lumen, from flowing through said diaphragm beyond said hub[;]

a needle attachment body removably connected to said hub[;] and

a cannulated catheter introducer needle having a sharp tip on a free end thereof and having an opposite end attached to said body such that said introducer needle has a least one position relative to said body which is operative to project through said diaphragm, hub lumen and catheter passageway when said body is attached to said hub for introducing said catheter into a liquid containing region of a biological organism, said introducer needle defining at least one fenestration on a central portion thereof which communicates with a cannula of said introducer needle and with said hub lumen and which is positioned distally of said diaphragm when said introducer needle is disposed in said operative position.

C. The Prior Art Supporting the Grounds of Unpatentability Instituted for Trial

Name	**Reference**	**Issue or Publication**	**Exhibit**
Fields	US 5,098,395	Mar. 24, 1992	Ex. 1002
Brimhall	US 5,697,914	Dec. 16, 1997	Ex. 1006
Enzmann	US 4,468,224	Aug. 28, 1984	Ex. 1007

D. The Grounds of Unpatentability Instituted for Trial

References	**Grounds**	**Claims challenged**
Brimhall	§ 102	31
Brimhall and Fields	§ 103	22, 23, 25, 26, 28, and 29
Brimhall, Fields, and Enzmann	§ 103	24

II. Discussion

A. Claim Construction

The Board will interpret claims using the broadest reasonable construction. 37 C.F.R. § 42.100(b); *see Office Patent Trial Practice Guide*, 77 Fed. Reg. 48,756, 48,766 (Aug. 14, 2012). There is a "heavy presumption" that a claim term carries its ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). By "plain meaning" we refer to the ordinary and customary meaning the term would have to a person of ordinary skill in the art. *In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007).

There are two exceptions to the general rule that a claim term is given its ordinary meaning: "1) when a patentee sets out a definition and acts as his own lexicographer, or 2) when the patentee disavows the full scope of a claim term either in the specification or during prosecution." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012). If an inventor acts as his or her own lexicographer, the definition must be set forth in the specification with reasonable clarity, deliberateness, and precision. *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed. Cir. 1998).

1. Flexible catheter

Both independent claims 22 and 31 recite "a flexible catheter." The '914 patent Specification does not shed any light on what "flexible" means, as used in conjunction with "catheter." In addition, neither party has directed us to any statements in the prosecution history that define the term.[2] Thus, for the purposes of the Decision to Institute, we adopted the common and ordinary meaning of

[2] Response to Office Action dated February 23, 1996 (Ex. 1008) and a Final Office Action, dated May 12, 1997 (Ex. 1009) are the only portions of the prosecution history which have been introduced into the official record.

"flexible." Neither party contests the construction adopted in the Decision to Institute, nor provides any additional evidence which would alter it. Thus, we determine,

> "Flexible" means "capable of bending easily without breaking."
>
> Ex. 3001, 1 (Oxford on-line dictionary (http://oxforddictionaries.com/us%20/definition/american_english/flexible)).

2. Flexible resilient diaphragm

Both independent claims 22 and 31 recite "a flexible resilient diaphragm." A diaphragm is "a thin sheet of material forming a partition." Ex. 3001, 3 (Oxford on-line dictionary (http://oxforddictionaries.com/us/definition/american_english/diaphragm)). This definition is consistent with the Specification which depicts diaphragm 34 as a thin partition. *See, e.g.*, Ex. 1001, Fig. 4.

In addition, the diaphragm is recited as being "flexible" and "resilient." Oxford's On-line Dictionary defines "flexible" as "capable of bending easily without breaking," whereas, "resilient" is defined as "able to recoil or spring back into shape after bending, stretching, or being compressed." Ex. 3001, 2 (Oxford On-Line Dictionary (http://oxforddictionaries.com/us/definition/american_english/flexible) and (http://oxforddictionaries.com/us/definition/american_english/resilient)). These definitions are consistent with the '914 patent which discloses that the diaphragm withstands being punctured by introducer needle 27 and remains liquid tight when the needle is retracted. Ex. 1001, col. 4, ll. 24–54. Claim 1 recites, "a flexible[,] resilient diaphragm which can be penetrated by a hypodermic needle, such as a catheter introducer needle," which is consistent with the definition of "flexible." *See also id.* at claim 34. Thus, the diaphragm is

"flexible" enough to be penetrated by an introducer needle and "resilient" enough to self-seal once the needle is withdrawn.

Petitioner asserts that "diaphragm" should not be limited to being "thin" because the specification does not explicitly limit the term to a particular thickness. Pet. Reply 2, n.2. Petitioner does not address the plain and ordinary meaning of "diaphragm," other than to state the Board should not rely on the dictionary. *Id.* In the absence of any new evidence to support a different construction, we see no reason to depart from the construction we adopted in our Decision to Institute.[3] Thus, we determine:

> "Flexible[,] resilient diaphragm" means a thin sheet of material forming a partition which is capable of bending or being penetrated by a needle easily without breaking and able to spring back into shape after being penetrated.

3. Between

Independent claim 22 recites that the "diaphragm [is] attached between [the needle attachment] body and a proximal end of said hub proximal to said side access port." In contrast, claim 31 recites that the "diaphragm [is] attached to said hub." Patent Owner's construction of "between" (i.e., "in a space that separates the needle attachment body and a proximal end of the catheter hub") does not address the issue squarely. Pet. 7. The issue is whether "between" the needle attachment body and hub requires the entirety of needle body 20 and the entirety of hub 14 to be located on opposite sides of diaphragm 34. For example, is

[3] We also note that Petitioner's objections are moot, because we find that even including "thin" in the construction, Petitioner has shown that the prior art at issue in this proceeding discloses a "diaphragm."

diaphragm 34, in Figure 3 of the '914 patent, "between" hub 14 and needle body 20?

The Specification does not explicitly or implicitly define "between." The Specification does state that the "diaphragm 34 may be removably disposed in the hub 14," or "may be contained in a housing . . . removably attached to the hub 14." Ex. 1001, col. 4, ll. 35–41. However, it is not clear if one, or both, of these diaphragm locations is considered "between" the hub and needle body. Likewise, nothing in the prosecution history of record speaks to the definition of "between." Thus, we determine that the broadest common and ordinary meaning of "between" which is "at, into, or across the space separating (two objects or regions)." Ex. 3001, 4 (Oxford On-Line Dictionary (http://oxforddictionaries.com/us/definition/american_english/between)). Under this definition, diaphragm 34, in Figure 3 of the '914 patent, is "between" hub 14 and needle body 20, as it is at, into, or across the space separating the hub and body.

III. ANALYSIS

A. Grounds Based on Brimhall

1. Brimhall (Ex. 1006)—Claim 31

Brimhall is a U.S. patent which was filed on March 16, 1995, and issued December 16, 1997. Brimhall describes a catheter assembly used to place an intravenous ("IV") catheter into a patient. Figure 4 of Brimhall is reproduced below with color and labels added for the convenience of the reader:

FIG–4

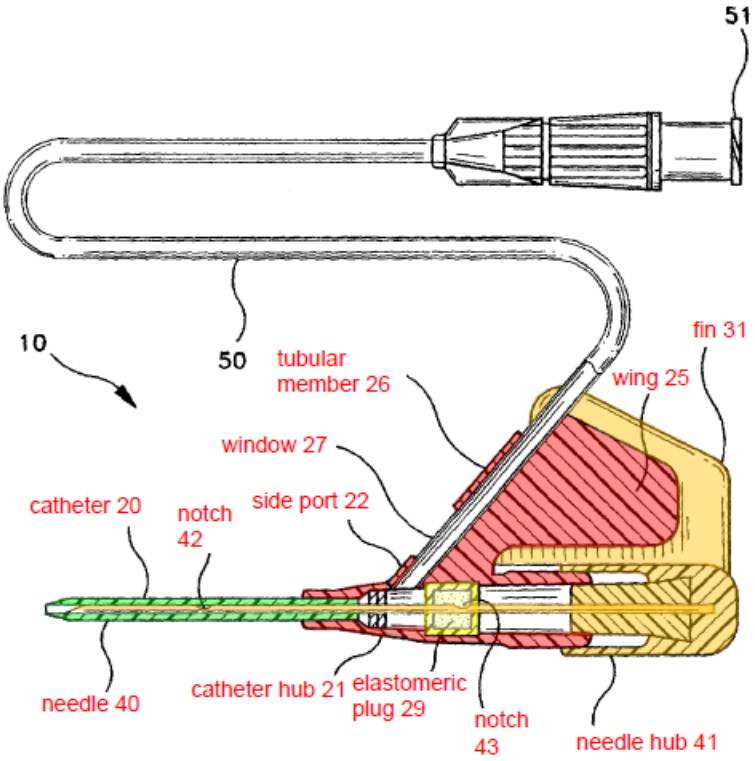

Figure 4 of Brimhall depicts a catheter assembly.

The Brimhall catheter assembly has four primary parts: catheter 20 (green), catheter hub 21 (red), needle hub 41 (orange), and side port 22 with extension tube 50. In use, needle 40 is advanced through elastomeric plug 29 via needle hub 41. Fin 31 is then rotated 90 degrees relative to wing 25. *See* Ex. 1006, Fig. 3. Needle 40 is then inserted into the patient and blood flashback may be observed at notch 42 if the catheter is clear and/or at window 27, as notch 43 allows blood to flow from the cannula of needle 40 into catheter hub 21. Note that elastomeric plug 29 prevents blood from flowing past catheter hub 21. Catheter 20 is then inserted into the patient while simultaneously holding the fin in place to prevent needle 40 from advancing further into the patient. The needle is retracted via needle hub 41 and

removed leaving catheter 20 and catheter hub 21 attached to the patient. Side port 22 may be used to attach an IV fluid supply. *Id.* at col. 3, l. 59–col. 4, l. 44.

2. Alleged anticipation of claim 31

Petitioner asserts that claim 31 is anticipated by Brimhall. Pet. 27–29. Patent Owner only argues that Brimhall does not disclose the recited "flexible, resilient diaphragm." PO Resp. 8–12; Tr. 20, 23. In its claim chart of Brimhall, Petitioner identifies column 3, lines 22 to 25 and lines 52 to 55 as well as Figures 2 and 4 as disclosing a flexible resilient diaphragm. Pet. 29. These passages disclose elastomeric (e.g., silicone) plug 29 located at the proximal end of catheter hub 21 to prevent liquid flow past access port 22. Introducer needle 40, when placed in its operative position, as depicted in Figure 2, extends through the lumen of catheter hub 21 and through the passageway of catheter 20. It should be noted that elastomeric plug 29, through which the needle penetrates, is described as optionally being filled with silicone gel to prevent fluid leakage. *See, e.g.*, Ex. 1006, Fig. 4 and col. 4, ll. 38–44. Petitioner notes that while Brimhall does not state explicitly that catheter 20 is "flexible," it does state that "[n]eedle 40 provides column strength to catheter 20 as it is advanced into the vein." Pet. 30; Ex. 1006, col. 4, ll. 34–36.

Patent Owner asserts that Brimhall's plug is not a "diaphragm" because it is not thin and is not "resilient." PO Resp. 9–10. Patent Owner further argues that Brimhall's plug does not spring back into shape. PO Resp. 9–10. Patent Owner contends that this is why Brimhall's plug is filled with a gel to seal the hole left by the needle when it is removed. PO Resp. 9–10. Patent Owner asserts that in the embodiments shown in Figures 2, 4, 7, and 8 of Brimhall, the elastomeric plug 29 is shown as substantially square with multiple sidewalls enclosing a volume that can contain gel. PO Resp. 10. Patent Owner also contends that at the time of the

invention, the art recognized a distinction between using a thicker sealing means, such as a plug, and a thin sheet, such as a diaphragm. PO Resp. 11. Patent Owner points to Wallace II[4] (Ex. 2001) as evidencing this recognized distinction. *Id.* Patent Owner contends that Wallace II warns against using a diaphragm in a catheter hub because it creates a "dead space," counseling to instead use an elastomeric plug. *Id.* Patent Owner asserts that the '914 patent "went against convention" by using a diaphragm which resulted in the surprising benefit of reducing needle drag, thereby providing improved tactile feedback. *Id.* at 6–7.

Petitioner counters that a person of ordinary skill would understand that the elastomeric plug of Brimhall is a thin elastomeric material that could be made thinner. Pet. Reply 3. Petitioner argues that Brimhall discloses that filling plug 29 with gel is optional, not required. *Id.* at 4–5 (quoting Ex. 1006, col. 4, ll. 38–40); Ex. 1015 ¶¶ 8–9. Petitioner contends that Patent Owner misinterprets the drawings of Brimhall by contending that the plug is "square." Pet. Reply 5. Petitioner also asserts that plug 29 of Brimhall is elastomeric and a person of ordinary skill in the art would understand it to be "flexible" and "resilient." *Id.* at 5–6; Ex. 1015, ¶ 11. Petitioner notes that Wallace II, the prior art cited by Patent Owner, acknowledges that elastomeric materials "compress shut" after being penetrated. Pet. Reply 6. Petitioner further points out that the '914 patent does not describe, nor suggest, a diaphragm is preferable to a thicker material, much less describe the surprising benefit alleged by Patent Owner. Pet. Reply 11.

As for Wallace II, Petitioner points out that the disclosure is focused more on the location of the diaphragm than its thickness. *Id.* at 12. Wallace II desired to reduce "dead space" in the catheter hub. *Id.* (citing Ex. 2001, 1, ll. 103–106).

[4] Wallace, GB 2 088 215 A, pub. June 8, 1982 ("Wallace II").

Petitioner asserts the dead space could be reduced simply by moving the diaphragm distally. *Id.* (citing Ex. 1015 ¶ 13).

We agree with Petitioner that Brimhall discloses a "flexible, resilient diaphragm" as recited in claim 31, for several reasons.

First, we find that Brimhall discloses that the plug can be made of an elastomeric material, and that, contrary to Patent Owner's assertions, a person of ordinary skill would understand that Brimhall's plug would be "flexible" and "resilient," because it is made from an elastomeric material. Ex. 1015 ¶ 11.

Second, we agree with Petitioner that a person of ordinary skill would understand that Brimhall is not limited to thick "plugs," as Patent Owner contends, but also would disclose the use of diaphragms to a person of ordinary skill.

Contrary to Patent Owner's contentions, we can find nothing in Brimhall, nor has Patent Owner cited to any portion of Brimhall, that requires that the plug be thick. Brimhall only discloses that elastomeric plug 29 "ensure[s] that fluid does not leak out of the proximal end of catheter hub 21." Ex. 1006, col. 3, ll. 22–25. As Petitioner's expert, Dr. Thomas Vesely, explains, a person of ordinary skill would understand that Brimhall only requires that the "plug" accomplish the function of preventing fluid from leaking out of the proximal end of the catheter hub. Ex. 1015 ¶¶ 7 (citing Ex. 1006, col. 3, ll. 22–25), 9.

Patent Owner's reliance on the Wallace II reference (Ex. 2001) does not convince us that this understanding of the scope of Brimhall's disclosure is incorrect, or that the term "plug" requires that the structure be thick. We agree with Patent Owner that Wallace II recognizes certain problems with the use of diaphragms, including "dead space" on the distal side of the diaphragm in certain configurations. Ex. 2001, 1, ll. 33–45. We also agree with Patent Owner that Wallace II proposes the use of "a self-sealing elastomeric plug whose distal end

terminates adjacent to the junction with the side limb" to solve this problem. Ex. 2001, 1, ll. 102–106. Yet, we do not agree with Patent Owner that this passage discloses a distinction between sealing mechanisms, such as elastomeric plugs and diaphragms. PO Response 11. To the contrary, we find all that these statements in Wallace II teach are that an elastomeric plug of a certain thickness — i.e., one that terminates adjacent to the junction with the side limb — can solve the defined problem of "dead space." This disclosure does not establish that all plugs are thicker than diaphragms. As discussed below, the Kontos patent[5] (Ex. 1020) explains that "plug" is a generic term that encompasses a broad range of structures. Thus, we are not persuaded that Wallace II establishes some distinction between plugs, generally, and diaphragms.

In determining whether a prior art reference discloses the claimed subject matter under 35 U.S.C. § 102, "it is proper to take into account not only specific teachings of the reference[,] but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826 (CCPA 1968). Petitioner has shown that the art considered a diaphragm merely a type of plug, and that all types of plugs can act to prevent fluid from leaking out of the proximal end of the catheter hub. For example, the Kontos patent (Ex. 1020) discloses that "[v]arious reseal plugs are used in intravenous catheter devices, and are well known for the purpose of preventing the escape of fluids from the catheter in addition to allowing penetration by a needle for delivery of the medicament of the patient." Ex. 1020, col. 1, ll. 25–29. Kontos further discloses that a diaphragm is one type of these "well known" reseal plugs, stating that: "[a] catheter with a

[5] Kontos, US 4,261,357, iss. Apr. 14, 1981.

reseal plug generally has the plug, such as a thin rubber diaphragm, covering the open end of the catheter hub." Ex. 1020, col. 1, ll. 32–34.

Based on the evidence above, we agree with Petitioner and find that a person of ordinary skill would have understood that Brimhall, by disclosing plugs generally, also disclosed specific types of plugs, including diaphragms. *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1380 (Fed. Cir. 2001) ("[T]he disclosure of a small genus may anticipate the species of that genus even if the species are not themselves recited."); *see also In re Petering*, 301 F.2d 676, 681(CCPA 1962) ("[I]t is immaterial that [the reference] d[oes] not expressly spell out the limited class . . . one skilled in this art would, on reading the [reference], at once envisage each member of this limited class, even though this skilled person might not at once define in his mind the formal boundaries of the class").

In sum, we hold that Petitioner has shown, by a preponderance of the evidence, that all the elements of claim 31 are disclosed in Brimhall, and thus, claim 31 is anticipated by Brimhall, under 35 U.S.C. § 102(b).

B. Obviousness Grounds Based on Brimhall Combinations—Claims 22, 23, 24, 25, 26, 28, and 29

Petitioner argues that independent claim 22 is very similar to independent claim 31, but notes claim 22 adds "a side access port," which Petitioner argues is disclosed in Brimhall as side port 22. Pet. 38–39. In addition, Petitioner points out that in claim 31 the "flexible resilient diaphragm" is "attached to said [catheter] hub," whereas in claim 22 it is "attached between [the needle attachment] body and a proximal end of said hub proximal to said side access port." Pet. 40. Petitioner

relies upon the disclosure of Fields for the disclosure of the diaphragm being "between" the body and hub. Pet. 41.[6]

1. Fields (Ex. 1002)

The catheter assembly of Fields has three primary portions: catheter 34 (green), second connection member 28 (red), and first connection member 12 (orange). Figure 1 of Fields is included below with color and labels added for the convenience of the reader.

Figure 1 of Fields is reproduced below with color and labels added:

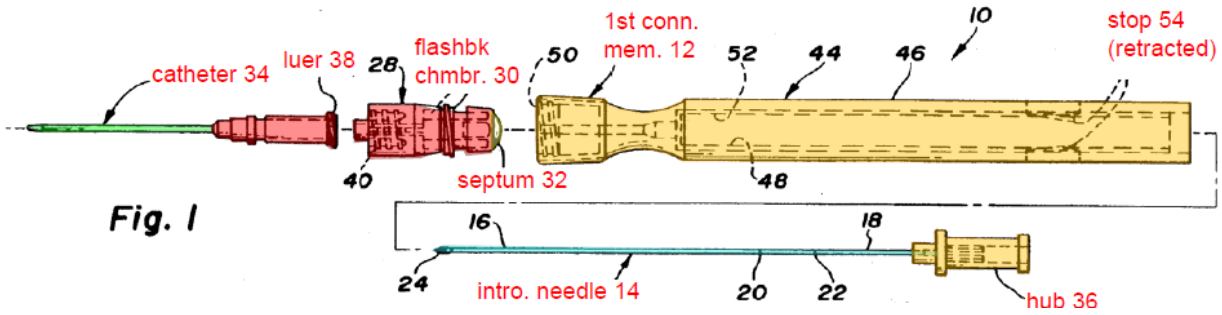

Figure 1 of Fields shows the components of a catheter assembly.

In use, stop 54 is released and needle 14 advanced via needle hub 36. As needle 14 is advanced, it passes through septum 30 (yellow). The needle is inserted in the patient and blood flashback can be observed in flashback chamber 30 as needle 14 contains openings 20, 22 which allow blood flowing up the needle cannula to fill the flashback chamber. Note that septum 32 prevents the blood from flowing past second connection member 28. The catheter is then inserted into the patient and needle 14 retracted. First and second connection members 12,

[6] Given the definition of "between" (i.e., "at, into, or across the space separating (two objects or regions)" plug 29 may be "between" needle hub 41 and catheter hub 21.

28 are removed, leaving catheter 34 attached to the patient. Ex. 1002, col. 3, l. 36–col. 4, l. 29.

Figure 3 of Fields is an enlarged partial sectional view of the connector illustrating the positioning of the first and second openings in the flashback chamber when an opening in a patient's view is established. Figure 3 of Fields is reproduced below with Septum 32 indicated in red to highlight the structure:

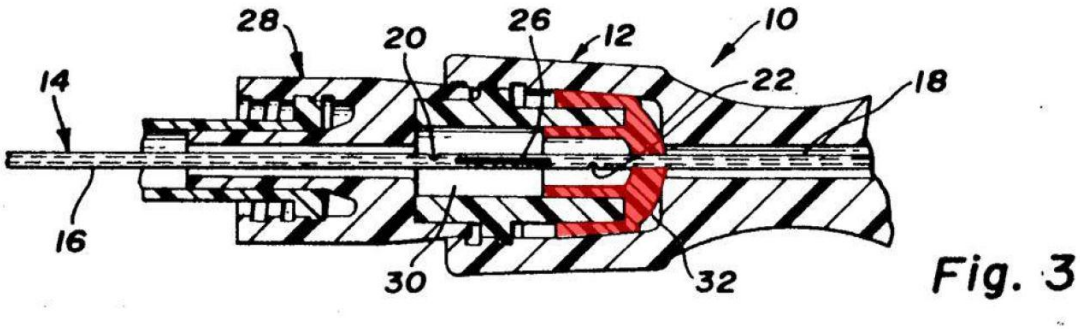

Fig. 3

Figure 3 of Fields shows a partial cross section of a catheter assembly.

While Fields does not disclose directly a side access port, it does incorporate Fields II[7] by reference. Ex. 1002, col. 3, ll. 24–28. As depicted in Figure 3, which is reproduced below, Fields II does disclose a side access port 44. Ex. 1012.

Figure 3 of Fields II is reproduced below:

[7] Fields, US 5,088,984, iss. Feb. 18, 1992 ("Fields II").

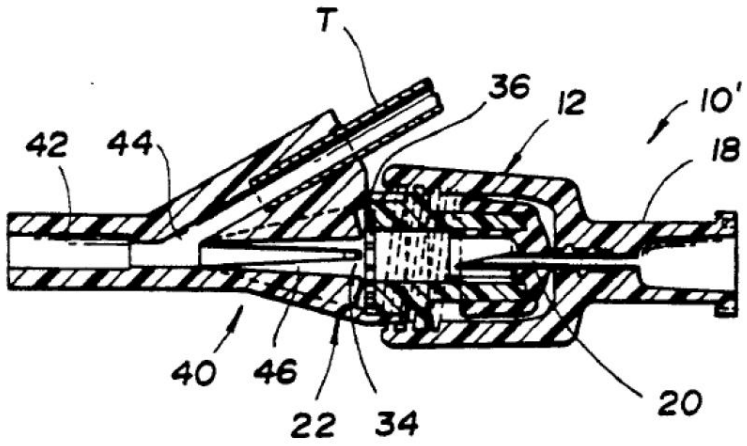

Fig. 3

Figure 3 of Fields II shows the cross section of a catheter assembly.

We also note that Fields II shows further detail regarding the septum. In Figure 3, Fields II shows a second connector member 22 having flashback chamber 26 and rubber septum 30. Figure 2 is reproduced below with rubber septum 30 highlighted in red.

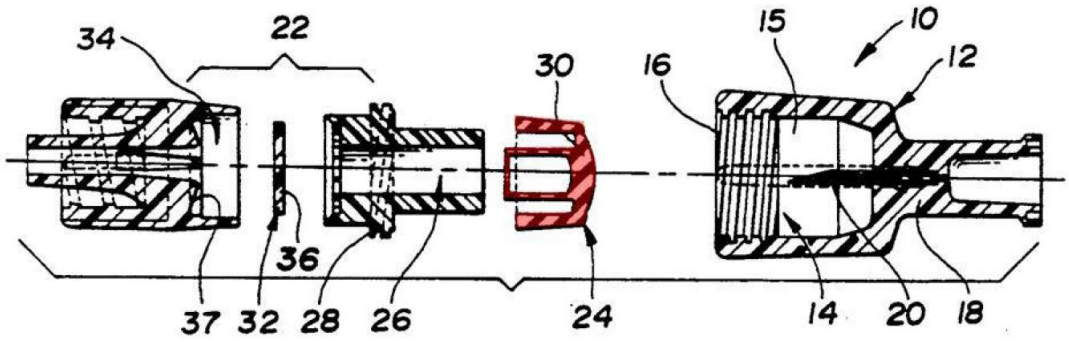

Fig. 2

Figure 2 of Fields II shows an exploded view of a catheter assembly.

2. Alleged Obviousness of Claims 22, 23, 25, 26, 28, and 29 in view of Brimhall and Fields

Petitioner argues that Brimhall discloses that "[t]he proximal end of catheter hub 21 is sealed with an elastomeric plug 29 . . . to ensure that fluid does not leak

out the proximal end of catheter hub 21." Pet. 41 (quoting Ex. 1006, col. 3, ll. 22–25). Petitioner further contends that the elastomeric plug 29 of Brimhall is attached completely within the catheter hub. Pet. 41. Petitioner argues that Fields discloses flexible, resilient septum 32 attached between first connector member/needle attachment body 12 and a proximal end of second connector member/hub 28. Pet. 41; *see* Ex. 1002, Fig. 1. Petitioner further argues that it would have been obvious to attach plug 29 of Brimhall between hub 21 and needle hub/needle attachment body 41 as shown in Fields and that doing so would still allow plug 29 to be penetrated by needle 40 and still prevent fluid spillage. Pet. 42.

Patent Owner asserts that Fields fails to disclose "a flexible, resilient diaphragm." PO Resp. 14–16. Specifically, Patent Owner asserts that septum 32 disclosed in Fields is too thick to be a "diaphragm." *Id.* at 14–15. Patent Owner asserts that Fields uses the term "membrane" when referring to thin sheets of material, and thus, "septum" must refer to a thick sheet of material. *Id.* (citing Ex. 1002, col. 4, ll. 6–8). Patent Owner also asserts that the '914 specification distinguishes "diaphragm" from "septum." *Id.* at 15 (citing Ex. 1001, col. 4, ll. 24–30 and col. 6, ll. 67–71). Lastly, Patent Owner contends that the patentee excluded "septums" from the claim scope during prosecution by changing "liquid sealing means" to "a flexible, resilient diaphragm." *Id.* at 15–16. At the oral hearing, Patent Owner further attempted to distinguish the septum of Fields by arguing that the septum was not a sheet because it was arched and included prongs that are inserted into the catheter. Tr. 23, 24.

Petitioner argues that Patent Owner seeks to define a septum as a "thick-walled plug," and then use that definition to demonstrate that Fields does not disclose a "diaphragm." Pet. Reply 8. Petitioner asserts that the septum 32 of

Fields is thin and that Patent Owner's assertions to the contrary are not supported by any evidence of record. Pet. Reply 10 (citing Ex. 1002, Figs. 1 and 3; Ex. 1015 ¶ 14). Petitioner also points out that Fields use of the term "membrane" is in reference to the permeability of a structure not its thickness. *Id.* at 10, n.3.

We agree with Petitioner that the septum of Fields discloses the "flexible, resilient diaphragm" recited in the claims. First, we agree that Petitioner has demonstrated that the '914 patent uses the terms "diaphragm" and "septum" interchangeably. *Id.* at 8–9. For example, structure 34 is identified as "a flexible, resilient diaphragm or septum 34." *Id.* (quoting Ex. 1001, col. 4, ll. 24–25); *see also* Ex. 1001, col. 6, l. 67–col. 7, l. 1 ("A flexible, resilient diaphragm or septum 84"). This supports a finding that the two terms have similar scope. *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009) ("The interchangeable use of the two terms is akin to a definition equating the two."). Thus, we do not agree with Patent Owner that the Specification somehow drew a distinction between these two terms.

Second, we are not persuaded by Patent Owner's assertion that a septum was excluded from the claim scope during prosecution. Patent Owner does not convincingly explain how changing "liquid sealing means" to "a flexible, resilient diaphragm" disavowed "septums." Indeed, Patent Owner admitted at the oral hearing that they were not aware of the issue of the differences between a diaphragm and a septum being discussed in the prosecution. Tr. 26. To operate as a disclaimer, the statement in the prosecution history must be clear and unambiguous, and constitute a clear disavowal of scope. *Microsoft Corp. v. Multi-Tech Sys., Inc.*, 357 F.3d 1340, 1356–57 (Fed. Cir. 2004). Here, there is simply no evidence of any disavowal, let alone evidence of a clear and unambiguous intent to exclude a septum from the meaning of a diaphragm.

Third, we find Fields II (which is incorporated by reference into Fields) describes the rubber septum as being flexible and resilient in a manner similar to how the '914 patent describes the diaphragm or septum as being flexible and resilient. *See* Ex. 1001, col. 4, ll. 24–35. In particular, we find that Fields II discloses that the rubber septum is "yieldable and adapted to be penetrated by a needle 20 when the first and second members 12, 22 are joined." Ex. 1012, col. 3, ll. 66–68. We further find that Fields II discloses that "[t]his connection [between first and second members 12, 22] is accomplished without spillage and the rubber septum 30 spontaneously closes when the first and second connectors 12, 22 are separated and the needle 20 is withdrawn from the rubber septum." *Id.* at col. 4, ll. 3–7. Thus, we find that the evidence supports a finding that the septum of Fields is "flexible" and "resilient" as recited in the claims of the '914 patent.

Fourth, we agree with Petitioner that the Figures shown in Fields disclose a diaphragm to one of skill in the art. A drawing teaches all that it reasonably discloses and suggests to a person of ordinary skill in the art. *In re Aslanian*, 590 F.2d 911,914 (CCPA 1979). While patent drawings not designated as being drawn to scale cannot be relied upon to define precise proportions of elements if the specification is completely silent on the issue, *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956 (Fed. Cir. 2000), this does not mean, "that things patent drawings show clearly are to be disregarded." *In re Mraz*, 435 F.2d 1069, 1072 (CCPA 1972). We find that Figures 1 and 3 of Fields disclose a partition consisting of a flexible sheet that is thin relative to the other components of the catheter assembly in Fields.

In contrast, we find that Patent Owner's interpretation of the drawings of Fields and Fields II is of little value. Patent Owner provides no metric or explanation of what a person of ordinary skill would understand to be "thin."

Thus, Patent Owner's bare comparisons between the drawings of the references and drawings of the '914 patent are not persuasive evidence particularly given the expert testimony and other evidence equating a septum to a diaphragm. *In re Wright*, 569 F.2d 1124, 1127 (CCPA 1977) ("Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value."); *In re Olson*, 212 F.2d 590, 592 (CCPA 1954).

Fifth, we find credible the testimony of Petitioner's expert, Dr. Vesely, that a person of ordinary skill would understand that the septum of Fields discloses a diaphragm as claimed in the '914 patent. Ex. 1015 ¶ 14. We agree with Dr. Vesely that the "thinness" and "thickness" must be assessed relative to some measure and that the measure relied upon by Dr. Vesely, the catheter hub, was reasonable. *See id.*

Finally, we have considered Patent Owner's new arguments that the septum disclosed in Fields is not a diaphragm because it is "arched" and has appendages to fix it to the hub. We find that these arguments are not persuasive, because there is nothing in the construction we have adopted that requires a diaphragm be flat or prevents the diaphragm from having additional structures attached to it.

Thus, we find that Petitioner has shown, by a preponderance of the evidence, that Fields discloses a "flexible, resilient diaphragm" as recited in the claims.

Patent Owner also argues that one of ordinary skill in the art would not have had a reason to substitute a flexible, resilient diaphragm for elastomeric plug 29 of Brimhall or rubber septum 30 of Fields. PO Resp. 17–18. As we determine that both elastomeric plug 29 of Brimhall and rubber septum 30 of Fields constitute flexible, resilient diaphragms, no substitution is necessary. However, if substitution was necessary, we agree with Petitioner that the substitution of a septum for a plug would have been merely the substitution of one known element

for another known element in the field to obtain a predictable result. In this case, the substitution of a septum for a plug simply would have substituted one well-known sealing means for catheter assemblies to prevent fluid flow for another well-known sealing means. Ex. 1015 ¶ 15.

Thus, we hold that Petitioner has shown, by a preponderance of the evidence, that claims 22, 23, 25, 26, 28, and 29 are unpatentable over Brimhall and Fields under 35 U.S.C. § 103(a).

3. Alleged Obviousness of claim 24 over Brimhall, Fields, and Enzmann

Claim 24 further limits claim 22 by reciting, "further comprising a multi-position stopcock operatively connected to said access port for selectively closing said access port in a liquid tight manner to prevent the flow of a liquid from said hub lumen through said access port." Petitioner alleges that Enzmann discloses stopcock 75 for selectively closing access ports 76, 77. Pet. 52; (*citing* Ex. 1007, Fig. 8). Petitioner further argues that it would have been obvious to use a stopcock like that disclosed in Enzmann to control the flow of fluid through side port 22 of Brimhall. Pet. 53. Petitioner contends that stopcocks were well-known structures in catheter assemblies used to direct the flow of fluid. Pet. 52, 53 (citing Ex. 1004 ¶ 120). Petitioner notes that Brimhall in view of Fields discloses a catheter system with a side port configuration for fluid flow. Pet. 53. Petitioner argues that the addition of a stopcock to the side port of Brimhall and Fields would have been obvious to one of ordinary skill "to predictably control the flow of fluid." Pet. 53.

Patent Owner asserts that Enzmann does not rectify the shortcomings of the Brimhall and Fields combination. PO Resp. 19. As indicated above, we do not find the combination of Brimhall and Fields lacking.

We agree with Petitioner that the addition of a stopcock to control fluid flow on the side port of Brimhall and Fields would have been the combination of familiar elements according to know methods to yield predictable results. *See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 416 (2007). Thus, we hold that Petitioner has shown, by a preponderance of the evidence, that claim 24 is unpatentable over Brimhall, Fields, and Enzmann under 35 U.S.C. § 103(a).

IV. CONCLUSION

Petitioner has shown by a preponderance of the evidence that: (1) claim 31 is unpatentable under 35 U.S.C. § 102(b) as anticipated by Brimhall; (2) claims 22, 23, 25, 26, 28, and 29 are unpatentable under 35 U.S.C. § 103(a) over Brimhall and Fields; and (3) claim 24 is unpatentable under 35 U.S.C. § 103(a) over Brimhall, Fields, and Enzmann.

V. ORDER

In consideration of the foregoing, it is hereby

ORDERED that Petitioner has shown by preponderance of the evidence that Claims 22–26, 28, 29, and 31 of the '914 patent are unpatentable; and

FURTHER ORDERED that because this is a final written decision, parties to the proceeding seeking judicial review of the decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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